



### Chromatography services offered in Switzerland

- **An insight by Gerd Osswald**

Manager Chromatography Services at CARBOGEN AMCIS AG

CARBOGEN AMCIS is not only a CMO providing development and manufacturing capacities for synthetic chemistry but also for chromatographic purification. Preparative chromatography capabilities have been developed and optimized over the last 25 years. Our experts are able to guide customers through extensive centralized solutions, with the goal to tailor an optimal preparative chromatography program; all based around project objectives, at every stage of the drug development cycle.

- **Chromatography services to reach purity targets**

The amount of projects where chromatography is involved and classical purification techniques fail increases steadily. Even though the ratio of the small molecules and biologics shows for the approved new chemical entities no unambiguous trend towards biologics or large molecules, the small molecules are getting more complex and often require chromatographic purification to reach the purity targets.

Our cross functional team with expertise in chromatography, analytics and cGMP production offers a diverse range of services. This includes method development for preparative chromatography, implementation of purification processes on scale, conducting process validation of chromatography processes, supporting containment facilities in implementation of chromatography of highly potent compounds, method transfer and technical assistance of large scale chromatographic purifications within the different CARBOGEN AMCIS sites.

- **Achiral Chromatography**

We offer a complete range of different separation techniques: Normal phase (NP), reversed phase (RP), ion exchange (IEX), hydrophilic interaction (HILIC) and solid phase extraction (capture and elute) from screening to purification of up to 500 kg.

- **Normal phase** for purification of apolar compounds
- **Reversed phase** for purification of polar & apolar compounds
- **Ion exchange** for purification based on ionic strength / pH effects
- **Hydrophilic interaction:** HILIC chromatography for polar compounds, e.g. biomolecules
- **Solid phase extraction:** simple separation of target compound from dissimilar matrix

Further, we also offer impurity isolation services supporting process research and development as well as process validation departments.

### •• **Chiral Chromatography**

Chiral Chromatography is used to support customers in fast resolution of enantiomers and ensures to reach >99% enantiomeric excess also for cases where chiral synthesis, enzymatic resolution or chiral resolution by crystallization or derivatization are not straight forward or do not fulfill the purity requirements.

Continuous separation by “simulated moving bed” (SMB) chromatography is suitable for cost effective separation at 1-50 kg scale. This allows to separate binary systems where typically no achiral purification effect is achievable and also results in less solvent costs compared to batch separation. For SMB under GMP conditions, there are 2 skids with 10 x 4.8 cm ID Columns suitable for continuous separation of 1-100 kg in 24hrs/7days mode available. We also offer classical batch separation by chiral HPLC, suitable for mg to kg scale, where additional achiral purification effects are possible.

### •• **Nanofiltration/Ultrafiltration (NF / UF) and Lyophilization**

Nano- and Ultrafiltration is a fast and cost effective technique especially useful for sensitive biomolecules. This is suitable for compounds like peptides, carbohydrates or sensitive biopolymers, where concentration of aqueous solutions by distillation would lead often to decomposition and is long lasting. We have two large scale NF / UF skids for membrane winding modules of different pore size suitable for 1 – 200 kDa cut off. Up to 800 L/h flow rate and 1-20 kg/day productivity and one medium scale NF / UF skid (GMP).

Lyophilization is the perfect supplement for products processed by nano- or ultrafiltration to bring the concentrates into a solid form. Alternatively its very suitable for chromatography fractions which were concentrated after purification by a solid phase extraction. Both techniques are very suitable for sensitive compounds and complement each other very well. At CARBOGEN AMCIS we have four tray lyophilizers of up to 30 kg ice capacity per run, suitable for nonHiPo and HiPo products (GMP).

### •• **Chromatography services equipment at CARBOGEN AMCIS**

Due to constant growth in number of projects and also more severe requirements regarding purity and separation, CARBOGEN AMCIS invests in the expansion of the chromatography capabilities to meet customer's expectations and offer state-of-the-art solutions. To ensure quality, we use self packed columns with commercial bulk stationary phase performed on site. We are able to perform preparative separation under cGMP from g to 100 kg scale.

Certain systems and columns are designated for purification of highly potent compounds, where we use columns up to 15 cm ID and a HPLC skid for HPLC purification. There are 40 cm ID cartridges and pump-skids for medium pressure chromatography available as well.

Our equipment and capabilities allow us to offer a wide range of chromatography services for GMP-production.

### Preparative HPLC:

- 5 Skids for 5 cm & 10 cm ID columns (non HiPo and HiPo)
- 3 Skids for 5 cm, 10 cm & 15 cm ID columns (non HiPo and HiPo)
- 1 Skid for 20 cm ID columns (non HiPo)
- 1 Skid for 30 cm & 45 cm ID columns (non HiPo)
- 1 Skid for 30 cm & 45 cm ID columns (in construction)

### Flash chromatography (LPLC & MPLC)

- Biotech: 3 skids for 40 cm ID cartridges (nonHiPo and HiPo)
- Flash column with 45 cm ID (non HiPo)
- 3 low pressure glass columns 20 cm ID (nonHiPo and HiPo)
- Large scale flash column (300 L & 800 L)

Further, we do have additional capacities for development, impurity isolation and small-scale nonGMP production.

- **Screening units:** >10 Agilent 1200 series HPLC units for method development together with column changers and partly with fraction collection unit
- **Analytical HPLC and UPLC:** for fraction analytics and IPC control during manufacturing within chromatography services department
- **Semipreparative flash and HPLC systems:** > 10 nonGMP systems for 1-5cm ID columns used for method development, scale-up and impurity isolations and proven acceptable range parameter studies.
- **NF / UF** membrane screening units
- **Flask and tray lyophilizers** with up to 16 kg ice capacity per run.



For more information about CARBOGEN AMCIS visit:  
[www.carbogen-amcis.com/chromatography](http://www.carbogen-amcis.com/chromatography)

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